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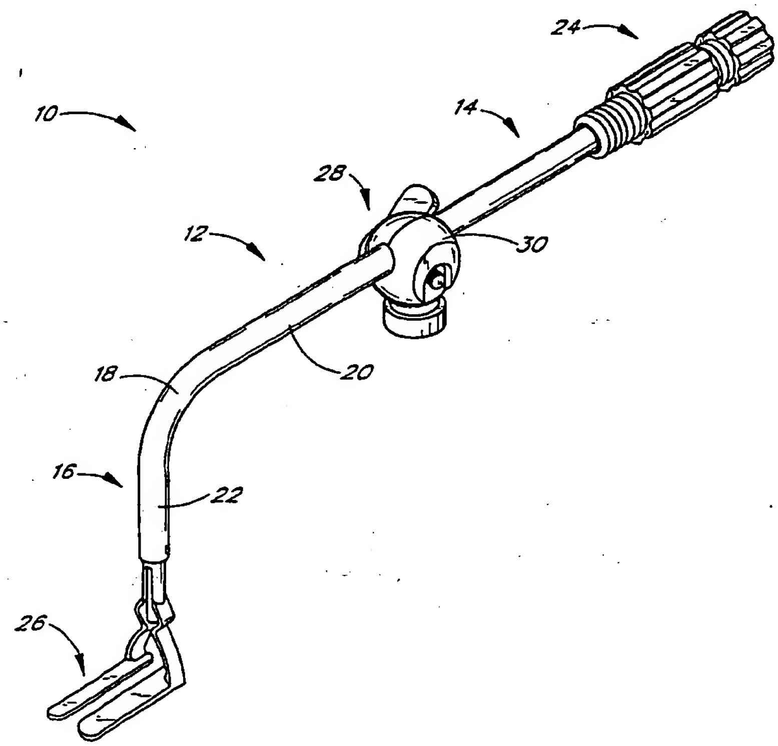
(54) Title: STABILIZER

(57) Abstract

The present invention is a tool (10) for stabilizing a portion of the heart upon which cardiac surgery is to be performed. The tool (10) includes an elongated shaft (12) with a distal end (14) which remains outside of the body of the patient, and a proximal end (16) which is inserted into the body of the patient. The tool (10) includes a control mechanism (24) attached to said distal end (14) of said shaft (12), and an engagement member (26) is attached to the proximal end (16) of the shaft (12). The engagement member (26) includes one or more prongs (142) which engage the heart proximate the location where the surgery is to be performed. The control mechanism (24) used to adjust the distance between the prongs (142), and the prongs (142) have a generally thin smooth portion which engages the heart.



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STABILIZER

Background of the Invention

The present invention relates generally to the field of surgical instruments and, in particular, to a stabilizer used during heart surgery.

During a conventional surgical procedure, a mechanical retractor is often used to hold various organs and tissues away from the body part upon which the surgery is to be performed. By holding these other organs and tissues out of the way, the retractor provides access and visibility of the desired body part to the surgeon. The retractor is often held by the surgeon or the surgeon's assistant, which quickly becomes a very tiring procedure because the retractor must be held in a relatively stationary position and the retractor must be carefully used so as not to damage the tissues or organs surrounding the surgical site.

A retractor may be used during conventional surgery in which a relatively large incision is made in the patient and the retractor is inserted through the large incision, or a retractor may be used during laparoscopic surgery in which one or more relatively small incisions are made in the patient and the retractor is inserted through the small incision. A conventional retractor used during laparoscopic surgery is disclosed in U.S. Patent No. 5,152,279 issued to Wilk. The Wilk patent discloses a retractor including an elongated frame and a substantially rigid retractor member movably mounted to the frame. The Wilk patent explains that during surgery, some internal organs or tissues are disposed under other organs when the patient is lying on his or her back (a normal posture during surgery). The overlying or adjacent organs and tissues must be lifted or displaced prior to operating on the desired organ. The Wilk patent discloses using the substantially rigid retractor member to displace these overlying or adjacent organs to provide access to the desired surgical site. Thus, the Wilk patent discloses a retractor that pushes away the tissues and organs surrounding the surgical site.

Another retractor is disclosed in U.S. Patent No. 5,293,863 issued to Zhu, et al. The Zhu patent discloses a bladed endoscopic retractor for use during endoscopic surgery in which bladed instruments located inside the patient's body are manipulated by controls located outside the body. Specifically, the blades are movably connected at one end to the inside of a tubular body, and the other ends of the blades are free to retract the various organs and tissue. The Zhu patent explains the purpose of the retractor blades is to push the surrounding tissues and organs away from the operating area. The Zhu patent defines the movement of the neighboring tissues and organs in one direction by the bladed endoscopic retractor while another instrument performs the surgery on the desired tissue or organ as counter traction.

There is a need for a convenient and practical device which stabilizes the heart during cardiac surgery.

Summary of the Invention

The invention is generally related to a stabilizer for holding a portion of an organ or tissue in a relatively stable position while surgery is performed on that body part and, in particular, to a stabilizer used during cardiac surgery.

One aspect of the invention is a device which engages a portion of an organ upon which surgery is to be performed, and holding that portion of the organ in a relatively stable position. Advantageously, the invention is used

during cardiac procedures to hold a portion of a beating heart in a relatively stable position. This invention simplifies a complex operation because it allows surgery on a beating heart. This saves much time and effort of the surgeon in comparison to convention surgery which requires that the heart be stopped or arrested.

Another aspect of the invention is it can be utilized during open heart surgery. During open heart surgery, using conventional techniques, the sternum is cut longitudinally (a median sternotomy) to provide access between opposing halves of the anterior portion of the rib cage. Alternatively, open heart surgery may be performed by a lateral thoracotomy wherein a large incision is made between two ribs and the ribs are retracted apart. A portion of one or more ribs may be permanently removed to optimize access. The present invention can be used in conjunction with either a median or lateral sternotomy to provide increased access to the heart.

Yet another aspect of the invention is it can be utilized during minimally invasive heart surgery. During this type of surgery, several small incisions and various cannulae are placed in the chest wall to obviate the need for a gross thoracotomy in which a large opening is created in the thoracic cavity. This technique avoids the trauma and complications which often result from the large incision required during conventional open heart surgery. The present invention can be used with minimally invasive surgery to provide increased access to the heart.

In another aspect of the invention, stabilization of the heart is accomplished by one or more prongs which engage the outer surface of the heart proximate the area the surgery is to be performed. The prongs are primarily flat, thin supporting members which are manipulated by a control mechanism located away from the surgical site. The prongs, when in the non-use position, are aligned or placed adjacent to each other, thereby aiding in the ease of installing the retractor into the patient's body. When it is desired to stabilize the portion of the heart upon which surgery is to be performed, the control mechanism is used to manipulate the positioning of the prongs.

In a still further aspect of the invention, the stabilizer preferably can be fastened to a support surface such as another surgical instrument to hold the stabilizer in a stationary position, and more preferably, the stabilizer is releasably fastened to a retractor by a universal joint. The universal joint is especially advantageous because it allows the stabilizer to be placed in a variety of different positions and then locked into the desired position.

A further aspect of the stabilizer is it provides increased flexibility for the surgeon because it is readily adjustable over a wide range, which allows it to be used with patients having a wide range of physical characteristics. The stabilizer can also be used during a variety of surgical procedures and the stabilizer can be adjusted during surgery. In addition, the stabilizer is quite small and is easily introduced into the body through a small opening. Further, the stabilizer is adaptable for use on hearts of various shapes and sizes by simply adjusting the size of the prongs and positioning of the stabilizer.

In a first embodiment of the invention, the stabilizer comprises an elongated shaft with a control mechanism at one end and one or more prongs attached to the other end. The prongs engage the heart proximate the location where the surgery is to be performed to hold the position of the heart in a relatively stable position.

In another embodiment of the invention, the tool comprises an elongated shaft with an engagement member connected at one end and a control mechanism attached at the other end. The control mechanism is located outside the body of the patient and controls the movement of the engagement member. Preferably, a connector is connected

to the elongated body to allow the tool to be attached to a supporting member or surface such as another surgical instrument.

In yet another embodiment of the invention, the stabilizer comprises an elongated body with one or more prongs connected at one end. The prongs support a portion of the heart during cardiac surgery. Preferably, a conduit is connected to each of the prongs and a vacuum is selectively applied through the conduit to engage the outer surface of the heart with the prongs. The vacuum provides positive engagement of the prongs with a portion of the outside surface of the heart. Advantageously, the vacuum helps prevent slippage or movement of the heart relative to the prongs. Significantly, the vacuum helps prevent trauma and injury to the heart because less pressure is applied to the outer surface of the heart by the prongs.

In still another embodiment of the invention, a method for using the present invention comprises the steps of providing a stabilizer with an elongated body and one or more prongs connected at one end of the body, forming an opening in the chest of the patient, inserting a portion of the stabilizer through the opening, manipulating the stabilizer so that the one or more prongs engage the desired portion of the organ to be operated.

Advantageously, the device is constructed from a few simple components which provide quick and easy assembly and disassembly. This allows all or a portion of the device to be readily sterilized or disposed.

Brief Description of the Drawings

These and other features of the present invention will now be described with reference to the drawings of preferred embodiments, which are intended to illustrate and not to limit the invention, in which:

Figure 1 is a perspective view of the left side of a stabilizer in accordance with an embodiment the present invention;

Figure 2 is a perspective view of the right side of the stabilizer shown in Figure 1;

Figure 3 is an exploded perspective view of the stabilizer shown in Figure 2;

Figure 4 is an exploded perspective view of the stabilizer shown in Figure 1;

Figure 5 is a top, plan view of the stabilizer shown in Figure 2;

Figure 6 is a right side view of the stabilizer shown in Figure 2;

Figure 7 is a front end view of the stabilizer shown in Figure 2;

Figure 8 is a cross-sectional side view along lines 8-8 of Figure 2, illustrating the cam lever in a first position;

Figure 9 is a cross-sectional side view of the stabilizer shown in Figure 8, illustrating the cam lever in a second position;

Figure 10 is a partial exploded perspective view of the stabilizer shown in Figure 1;

Figure 11 is a cross-sectional side view along lines 11-11 of Figure 5;

Figure 12 is a perspective view of another embodiment of a stabilizer;

Figure 13 is a cross-sectional side view along lines 13-13 of Figure 12;

Figure 14 is a cross-sectional side view of a portion of another embodiment of a stabilizer;

Figure 15 is a bottom view of a portion of the stabilizer shown in Figure 14, illustrating the feet;

Figure 16 is a perspective view of a portion of another embodiment of a stabilizer with a portion of the arm cut away, illustrating the feet in a closed position;

Figure 17 is another perspective view of the stabilizer shown in Figure 16, illustrating the feet in an open position.

Detailed Description of the Preferred Embodiment

Referring to the drawings, Figure 1 illustrates a preferred embodiment of a stabilizer 10 used during cardiac surgery. For example, when the stabilizer 10 is used during conventional open heart surgery, the front chest area of the patient is cut medially along the sternum with a scalpel and the sternum is opened with a saw to provide access to the thoracic or chest cavity area of the patient. The stabilizer 10 is inserted through the large opening in the chest wall. On the other hand, when the stabilizer 10 is used during minimally invasive heart surgery, the stabilizer 10 is inserted through a small opening or port created in the chest wall of the patient.

The stabilizer 10 is described below in conjunction with performing surgery on a beating heart, but the stabilizer may also be utilized during procedures in which the heart is arrest or stopped. Advantageously, using the stabilizer 10 on a beating heart instead of an arrested heart eliminates the complicated procedures for stopping blood flow through the heart and ceasing cardiac contractions which are required during conventional cardiac surgery. These complicated procedures often result in significant hospitalization and recuperation time, as well as much pain and trauma suffered by the patient. Significantly, when the stabilizer 10 is used on a beating heart, the stabilizer does not disrupt the natural rhythm of the heart, stop blood flow to the heart or damage the coronary arteries. Instead, the stabilizer 10 holds a portion of the heart in a relatively stable position for surgery, and only that portion of the heart is engaged by the stabilizer.

One skilled in the art will recognize that the stabilizer 10 can be used with organs and tissues other than the heart, and it can be employed with various surgical procedures. Thus, while the stabilizer 10 is described in detail as stabilizing a portion of the heart during minimally invasive surgery, the stabilizer 10 can also stabilize other body parts during a variety of surgical procedures.

The stabilizer 10, as shown in Figure 1, is used to engage a portion of the outer surface of a patient's heart, proximate the area upon which the surgery is to be performed. The stabilizer may be used in conjunction with a retractor, which pushes surrounding tissues and organs away from the surgical site. The stabilizer 10 includes an elongated shaft or body 12 with a distal end 14 and a proximal end 16. The body 12 includes an elbow or bent section 18 which divides the body into a first section 20 and a second section 22. The elbow 18 preferably forms about a 90° angle between the first and second sections 20 and 22, but a larger or small angle may also be utilized depending, for example, upon the type of surgery to be performed or the size and physical characteristics of the patient. Alternatively, the body 12 may be generally straight, or the body 12 may include multiple bent or curved sections.

The body 12 has a tubular configuration with a generally circular cross-section. The body 12 is preferably constructed from a metal such as stainless steel or other metal alloy, but other materials, such as plastics and composites, may also be used. More preferably, the body 12 is constructed from a malleable material which allows

the surgeon to bend the sections 20, 22 or elbow 18 into the desired configuration. The diameter of the body 12 is between about 1/4 inch (.5 cm) and 3/4 inch (2 cm), and more preferably about 1/2 inch (1 cm); and the walls of the body 12 are relatively thin to form a relatively thin-walled tube. It will be understood the size and dimensions of the body 12 may vary according to the type of material used to construct the body, and the intended use of the stabilizer 10.

Additionally, all or a portion of the body 12 may be constructed from shape memory alloys which are materials, either plastic or metal, that are flexible at one temperature and generally rigid at another temperature. Desirably, the alloy is flexible at a temperature greater than body temperature (e.g., over 50°C) and generally rigid at about body temperature (37°C) or lower. Thus, the body 12 may be constructed from shape memory alloys which are generally rigid to facilitate inserting the stabilizer 10 into the body of the patient, but flexible when heated above body temperature. This allows the surgeon to heat and shape the body 12 into a configuration most suitable for use during surgery, and then cooled so that the body 12 maintains the desired shape.

The first section 20, second section 22 and elbow 18 may be individual members which are interconnected to form the body 12, but the body 12 is preferably integrally formed as a single member for increased strength and rigidity. The length of the first section 20 is preferably between about 4 inches (10 cm) and 18 inches (45 cm), and more preferably about 12 inches (30 cm). The length of the second section 22 is preferably between about 1 inch (2.5 cm) and 4 inches (10 cm), and more preferably about 2 inches (5 cm). Of course, the sections of the body 12 may be longer or shorter depending upon the desired used of the stabilizer 10 and the physical characteristics of the patient. Additionally, the body 12 may comprise multiple interconnected members or telescoping members which allow the length of the body 12 to be adjusted.

The stabilizer 10 also includes a control mechanism 24 connected to the distal end 14 of the body 12 and an engagement member 26 connected to the proximal end 16 of the body 12. As described below, the control mechanism 24 controls the movement of the engagement member 26 which is located at the opposite end of the body 12. The stabilizer 10 also includes a connector 28 located between the control mechanism 24 and the engagement member 26. The connector 28 allows the stabilizer 10 to be connected to a support member or surface such that the stabilizer is held in a relatively stationary position. The connector 28 advantageously allows the stabilizer 10 to be readily positioned in a variety of desired locations, and then locked into the desired location.

As best seen in Figures 3 and 4, the connector 28 comprises a universal joint 30 attached to the first section 20 of the body 12, but the connector may also be attached to the second section 22 or elbow 18 of the body 12. The universal joint 30 includes a clip 31 for mounting the stabilizer 10 to a support member such as a rib retractor (not shown). As seen in Figures 6, 8 and 10, attached to the bottom portion of the clip 31 are feet 32 for connecting the stabilizer 10 to the support. The feet 32 have an angled outer face 32A and the feet are spaced apart by a distance 32B. The feet 33 are preferably constructed from a slightly flexible material, such as plastic, to allow the feet to slightly deform when the clip 31 is attached to the support. This allows the feet to be connected to the retractor by a "snap" fit or interference fit. It will be appreciated that there are many different ways to connect the clip 31 to the support, and the feet 32 may have many different sizes and configurations

depending upon the method used to connect the clip to the support. As discussed above, the support desirably comprises another surgical instrument such as a retractor, but any supporting surface such as a railing of the operating table or equipment stand may be utilized.

As seen in Figures 3 and 4, the clip 31 is generally cylindrical and includes a base 33 with an upwardly extending wall 34. The upwardly extending wall 34 defines a central opening 36. Located proximate the center of the base 33 is a recess 35. The upper portion of the wall 34 includes a beveled lip 37 defining an annular grove 39, which is best seen in Figure 8.

The clip 31 is configured to receive a portion of a clamp seat 38, which has a generally cylindrical outer surface 40 with an annular groove 41. As seen in Figure 8, the beveled lip 37 of the clip 31 fits into the annular groove 41 to secure the clamp seat 38 into the clip 31. The clamp seat 38 includes a central opening 42 which extends through the seat 38 and the upper portion of the opening 42 includes a notch 44. The clamp seat 38 also includes a curved upper surface 46 to allow for rotation of the connector 28 about the clamp seat.

A pivot pin 48, with a generally rectangular upper portion 50 and a downwardly extending shaft 52, is configured to fit within the opening 42 in the clamp seat 38. The pivot pin 48 includes a projection 54 which is configured to fit within the notch 44 in the opening 42 of the clamp seat 38, and an annular groove 56 is located in the lower portion of the shaft 52. As seen in Figure 8, the pivot pin 48 is inserted through the opening 42 in the clamp seat 38 and a clip 58, or other type of fastener or lock, fits within at least a portion of the annular groove 56 to hold the pivot pin 48 within the clamp seat 38. The upper portion 50 of the pivot pin 48 extends above the upper surface of the clip 32 and is generally aligned with the first section 20 of the body 12.

As best seen in Figures 3 and 4, the universal joint 30 includes a first clamp housing 60 with a pair of notches 62 and 64 which are configured to receive one side of the body 12 of the stabilizer 10. The universal joint 30 also includes a corresponding clamp housing 66, with notches 68 and 70 to receive the other side of the body 12. The housings 60 and 66 are configured to be fastened about the body 12, and the housing may be connected by an interference fit, snap fit or any type of fastener. The lower portions of the housings 60 and 66 include openings 72 and 74, respectively, which are configured to receive the pivot pin 48.

The housings 60 and 66 include a pair of apertures 76 and 78, respectively, which are aligned to receive a cam lock 80. The cam lock 80 includes a central body portion 82, a first shaft 84 and a second shaft 86. The central body portion 82 is generally rectangular in shape, and is positioned between the housings 60 and 66 and beneath the body 12 of the stabilizer 10. The body portion 82 is preferably constructed from a slightly flexible material such as rubber or plastic, or includes a deformable cover or coating. The first shaft 84 includes one or more annular grooves 88, and the shaft is configured to extend through the aperture 76 in the housing 60. When the shaft 84 is inserted through the aperture 76, a clip 90 or other locking device is connected to the annular grooves 88 to prevent the unintended removal of the shaft 84 from the housing 60. The second shaft 86 also includes one or more annular grooves 92, and the shaft is configured to extend through the aperture 78 in the housing 66. When the shaft 86 is inserted through the aperture 78, a clip 94 or other locking device is connected to the annular grooves 92 to prevent the unintended removal of the shaft 86 from the housing 66.

A cam lever 100, which contains an aperture 102 through which the end of the first shaft 84 is inserted, is positioned between the first clamp housing 60 and the clip 90. The cam lever 100 includes a handle 104 with a curved portion 105 which is configured to fit around the exterior surface of the housing 60. The cam lever 100 is movable between a first position in which the universal joint 30 allows the body 12 to pivot about the pivot pin 48 and the length of the body 12 to move; and a second, locked position in which the body 12 is securely held at a desired position and the body 12 cannot rotate about the pivot pin 48.

As seen in Figures 8 and 9, the cam lever 100 is connected to the cam lock 80 and the cam lock 80 is pivotally mounted within the housings 60 and 66. As seen in Figure 8, in the first position, the rectangular portion 82 of the cam lock 80 is positioned between the pivot pin 48 and body 12, but the rectangular portion of the cam lock does not engage either the pivot pin 48 or the body 12. Thus, this first position allows the universal joint 30 to rotate and the body 12 is movable within the universal joint.

As seen in Figure 9, in the second position, the cam lever 100 has been rotated which causes the rectangular portion 82 of the cam lock 80 to pivot at about a 90° angle relative to the first position. In this second position, the rectangular portion 82 engages both the upper surface 50 of the pivot pin 48 and the body 12 to prevent rotation of the universal joint 30 and movement of the body 12 within the universal joint 30. As seen in Figure 9, the deformable surface of the rectangular portion 82 has deformed to create an interference fit with the body 12 and the pivot pin 48. Thus, in the second position, the cam lock 80 locks the body of the stabilizer 10 in the desired position.

As best seen in Figures 10 and 11, the control mechanism 24 includes a connecting member 110 with external threads 112 connected to the distal end 14 of the body 12. The threads 112 may be formed integrally with the body 12, or the connector 110 may be attached to the body by any known fastener, such as glue or epoxy. A height adjustment knob 114 with internal threads 115 is threadably connected to the external threads 112 of the member 110. The height adjustment knob 114 includes a plurality of radially outward extending ridges 116 configured to facilitate grasping of the knob 114 by the surgeon. As shown in Figure 9, the ridges 116 extend generally parallel to the length of the height adjustment knob 114, but the ridges may also have any other desired orientation, and a textured or smooth surface may also be utilized to allow the surgeon to rotate the height adjustment knob 114. The height adjustment knob 114 includes an extension 118 with external threads 120 extending from the end of the knob 114 opposite the body 14.

The external threads 120 of the extension 118 are configured to engage the internal threads 122 of a dial 124. The dial 124 includes a plurality of radially outward extending ridges 126 configured to allow grasping of the dial 124 by the surgeon. As shown in Figure 10, the ridges 126 extend generally parallel to the length of the dial 124, but the ridges may also have any other desired orientation, and a textured or smooth surface may also be utilized to allow the surgeon to rotate the dial 124. As described below, the control mechanism 24 allows the height of the engagement member 26 to be adjusted and allows the engagement member to be manipulated by controls located away from the surgical site. Preferably, the controls are located outside the body for easy access and manipulation of the controls by the surgeon.

As seen in Figure 10, located with the body 12 is a thin metal cable 130 which is positioned within a flexible tubular housing 132. The housing 132 has the same general shape as the body 12 and is sized slightly larger than the cable 130 to allow the cable to move freely within the housing. The housing 132 has an end 133 which is attached to the height adjustment knob 114, but the housing 132 may also be attached to the connector 110. The cable 130 includes a first end 134 which is attached to the dial 124 by an end piece 136. The end piece 136 is rotatably connected to the dial 124 to allow the dial to be turned without rotating the cable 130.

The flexible housing 132 is preferably rotatably connected to the height adjustment knob 114 so that when the knob is rotated, the housing does not rotate. Because the housing 132 is connected to the height adjustment knob 114, as the knob is rotated in one direction and moved away from the body 12, the knob 114 pulls a portion of the housing from the body 12. On the other hand, when the knob 114 is rotated in the other direction and moved towards the body 12, the housing 132 is pushed into the body 12. Similarly, when the dial 124 is turned in one direction and is moved away from the body 12, the dial 124 pulls the cable 130 away from the engagement member 26. Alternatively, when the dial 124 is rotated in the opposite direction and the dial is moved towards the body 12, the cable 130 moves towards the engagement member 26. As discussed below, the rotating of the knob 114 and dial 124 allows the height and positioning of the engagement member 26 to be adjusted.

As best seen in Figures 10 and 11, the second end 137 of the cable 130 is attached to a spreader 138 which fits within an opening 141 in the top of a stabilizer foot 140. The stabilizer foot 140 includes two outwardly extending prongs or tines 142 which are configured to engage the exterior surface of the heart. The stabilizer foot 140 may have more or less prongs depending upon the desired use of the stabilizer 10 and, as discussed below, the prongs may have a variety of different configurations. The stabilizer foot 140 is connected to the flexible housing 132 so that when the height adjustment knob 114 is turned and the housing moves within the body 12, the stabilizer foot also moves. Thus, by turning the knob 114, the vertical positioning of the stabilizer foot 140 and prongs 142 may be adjusted. Advantageously, this allows the force of the prongs 142 against the heart to be readily controlled by the surgeon.

The prongs 142 include a distal portion 144 and a proximal portion 146. The prongs 142 are relative thin, elongated blades with a generally smooth lower surface 148 and upper surface 150. The edges and ends of the prongs 142 are rounded or blunt such that the prongs do not irritate or lacerate the heart or surrounding tissues. The prongs 142 may also have a rounded upper and/or lower surface. Although not shown in the accompanying drawings, the prongs 142 may also have a slight curvature which is used to minimize or maximize the surface area engaged by the prongs. This curvature may extend from side-to-side or front-to-back of each prong 142. Further, as seen in Figure 7, the lower surface 148 of the prongs 142 may be at an angle to facilitate engagement of the prongs with the outer surface of the heart. It will be understood that the prongs 142 may have a variety of other configurations such as circular, curved or square; and the prongs 142 may have one or more openings to form, for example, a ring or grid. Additionally, the prongs 142 are preferably configured to be positioned parallel to the coronary artery. More preferably, a web or other structure is placed between the prongs 142 to restrict or stop

blood flow through the artery. Alternatively, the prongs 142 may be configured to engage or apply pressure to the coronary artery such that blood flow through the artery is constricted or stopped.

The prongs 142 have a curved upper portion 150 which forms a generally S-shaped member, but it will be appreciated that the upper portions 150 may be formed into numerous desired shapes and may be of different sizes. The prongs are normally biased into a closed position in which the prongs 142 and upper portions 150 are located generally proximate to each other. This facilitates inserting the prongs 142 through the incision and into the patient. In the closed position, the spreader 138 is positioned above the upper curved portions 150 of the prongs 142. When the surgeon rotates the dial 124 and the spreader 138 move downwardly, the spreader engages the curved portions 150 of the prongs and the spreader 138 forces the prongs apart. This also moves the feet of the prongs 142 apart. Alternatively, when the surgeon desires to move the prongs into the closed position, the surgeon rotates the dial in the opposite direction and the spreader 138 is lifted such that it no longer engages the curved portions 150 of the prongs.

The prongs 142 are desirably sufficiently rigid so as not to excessively bend or flex when engaging the outer surface of the heart. This allows the prongs to securely engage the heart. On the other hand, the prongs may be slightly flexible to avoid damaging or irritating the surface of the heart. The prongs 142 may be stamped out of thin pieces of metal, constructed from stainless steel or other alloys, or molded from various types of plastics or composites.

In another embodiment of the invention, as shown in Figures 12 and 13, a conduit 160A and 160B is attached to each of the prongs 142A and 142B. The conduits 160A and 160B include one or more apertures 162 which are aligned with one or more apertures 164 that extend through each of the prongs 142A and 142B. Preferably, there are three apertures 162 in each conduit 160A and 160B that are aligned with three apertures 164 in the prongs 142A and 142B. More preferably, as seen in Figure 13, the apertures 164 in the prongs 142A and 142B are tapered for secure engagement of the outer surface of the heart with the prongs. Of course, the conduits 160 and the prongs 142 may have a different number of apertures and the apertures may have a variety of different configurations.

The conduits 160A and 160B are connected to a vacuum source 166 by a conduit 162. Suction from the vacuum source is used to engage the prongs 142 of the stabilizer 10 with the outer surface of the heart. Advantageously, the prongs 142 of the stabilizer 10 do not have to be forcibly pressed into the outer surface of the heart, and the heart is less likely to be irritated or lacerated, because the vacuum creates a positive engagement between the prongs 142 and the outer surface of the heart. Additionally, the vacuum helps prevent slippage or movement of the heart and the prongs 142 may also be smaller in size, which results in less contact area and trauma to the heart because the vacuum creates a secure engagement with the desired portion of the heart. Desirably, the surgeon and/or assistant controls whether the vacuum is on or off and the amount of the vacuum.

In yet another embodiment of the invention, as shown in Figures 14 and 15, the stabilizer 10 includes a foot portion 170 connected to the proximal end 16 of the arm 12. The foot portion 170 includes a first foot 172 and a second foot 174 connected by an attachment member 176. The attachment member 176 has a first generally

planar surface 178 which is joined to the feet 172, 174 and a second generally planar surface 180 which is attached to a rod 182. The first surface 178 and second surface 180 of the attachment member 176 are joined at about a 90° angle, but the surfaces can also be connected at any desired angle. Additionally, the attachment member 176 is preferably constructed from a slightly malleable material so that the surgeon can adjust the positioning of the feet 172 and 174, but the attachment member is desirably sufficiently rigid such that it will not deform or bend during use.

The rod 182 is connected near the center of the second surface 180 of the attachment member 176. The rod 182 is preferably solid and has a length of about 1 inch (2.5 cm), but the rod can also be hollow, have different shapes or configurations, and be longer or shorter. Attached to the other end of the rod 182 is a ball 184 which is located within a socket 186. The ball 184 is preferably constructed from a synthetic material having a low-to-medium hardness, but it will be appreciated that the ball can be constructed from a wide variety of materials. Advantageously, as described below, the ball 184 and socket 186 allows the foot portion 170 to be placed in the desired position and then locked in place.

As seen in Figure 14, the socket 186 includes an outer tube 188 in which the ball 184 is located. The first end 190 of the outer tube 188 has a diameter slightly smaller than the diameter of the ball 184 to prevent the ball from unintentionally exiting the tube. The rod 182, which extends through the reduced diameter section 190 of the outer tube 188, can be permanently or releasably connected to the ball 184 and/or foot portion 170. The ball 184 is freely movable within the outer tube 188, but the reduced diameter section 190 of the outer tube prohibits full movement of the ball.

An inner tube 192 is located within the outer tube 188. The outside diameter of the inner tube 192 is slightly smaller than the inside diameter of the outer tube 188 so that the inner tube is slidable within the outer tube. The inner tube 192 has a proximal end 194 which is configured to selectably engage the ball 184. Desirably, the proximal end 194 has a sharp or "saw tooth" edge so that the inner tube 192 can securely engage the ball 184 to prevent the ball from moving. The distal end 196 of the inner tube 192 is attached by a connector 193 to an element 194 which extends through the arm 12 of the stabilizer 10. The other end of the element 194 is attached to a rotatable member (not shown) located at the other end of the outer tube 188. The rotatable member is configured such that when the member is rotated in one direction it pushes the element 194 and the attached inner tube 192 against the ball 184, thereby preventing the ball from rotating. When the rotatable member is rotated in the opposite direction, it moves the element 194 and inner tube 192 away from the ball 184, thereby allowing the ball to rotate freely. The element 194 is preferably a flexible, non-compressible cable which freely moves within the outer tube 188 and the inner tube is preferably a "flexible shaft" which readily deforms according to the shape of the outer tube 188. The outer tube 188 is a rigid member that can have any desired shape such as straight, curved, one or more angled sections, etc.

In use, when the surgeon desires that the foot portion 170 pivot freely relative to the arm 12 the rotatable member is adjusted such that first end 194 of the inner tube 192 is not engaged with the ball 184 and the ball freely moves within the socket 186. On the other hand, when the surgeon desires to prevent movement of the foot

portion 170, the rotatable member is adjusted such that first end 194 of the inner tube 192 is forced against the ball 184 to prevent the ball from moving. This causes the foot portion 170 to be held in a stationary position. In particular, because the ball 184 has a low-to-medium hardness, the sharp edges of the inner tube 192 securely engage or "bite" into the ball in order to resist movement of the ball. Therefore, the surgeon can position the foot portion 170 in the desired location and lock the feet in place.

This ball and socket joint advantageously permits the stabilizer arm 12 to have a wide variety of configurations. Specifically, the outer tube 188 can be formed into the desired shape; for instance, with one or more curved or angled sections. The flexible inner tube 192 and flexible member 194 then adapt to the configuration of the outer tube 188. Thus, the stabilizer can be shaped so that the feet engage the desired position of the heart.

Additionally, although not shown in the accompanying figures, the first end 190 of the outer tube 188 that contains the ball 184 could be removable. That is, the portion of the outer tube 188 that contains the ball 184 could be disconnected from the remaining portion of outer tube. Significantly, this allows the ball 184 and foot portion 170 to be repaired, replaced or interchanged with another ball and foot portion with different configuration. This removable section also facilitates reuse and sterilization of the stabilizer.

In another embodiment of the invention, as shown in Figures 16 and 17, the stabilizer 10 includes an adjustable foot portion 190 connected to the proximal end 16 of the arm 12. The foot portion 190 includes a first foot 192 and a second foot 194 which are connected to arms 196 and 198 respectively. The arms 196 and 198 are connected to a spring retainer 200 which is fixed to an outer tube 202. The outer tube 202 may be an integral part of the arm 12, or attached to the proximal end 16 of the arm. The spring retainer 200 is a resilient member which normally biases the foot portion 190 into an open or spaced apart position. Slidably mounted within the outer tube 202 is an inner tube or sleeve 204. The inner tube 204 includes slots 206 and 208 which allow the spring retainer 200 to be connected to the outer tube 202 and the slots allow movement of the inner tube within the outer tube. The distal end 210 of the inner tube 204 is attached to an element (not shown) which extends through the arm 12 of the stabilizer 10. The other end of the element is attached to a rotatable member located at the distal end of the outer tube 202. The rotatable member is configured such that when the member is rotated in one direction, it pushes the element and the attached inner tube 204 towards the foot portion 190. When the rotatable member is rotated in the opposite direction, it moves the element and the inner tube 204 away from the foot portion. The element is preferably a flexible, non-compressible cable which freely moves within the outer tube 202.

As shown in Figure 16, the inner tube 204 is in its normally closed position with the feet 192 and 194 positioned near each other. In this position, the inner tube 204 is located near the foot portion 190 and the arms 196 and 198 are positioned within the inner tube. The feet 192 and 194 may also be placed in an open position as shown in Figure 17. In the open position, the inner tube 204 is moved away from the foot portion 190 and the spring retainer 200 forces the arms 196 and 198 and feet 192 and 194 apart.

Advantageously, the stabilizer 10 can easily be inserted into the body while the feet 192 and 194 are in the closed position. After the proximal end 16 of the arm 12 is placed in the body, the surgeon can then turn the rotatable member to spread the feet 192 and 194 into the open position. Desirably, the surgeon can adjust the

stabilizer such that the feet 192 and 194 are separated by the desired distance. Further, the surgeon can open the feet 192, 194 and then close the feet around a desired portion of the body, such as the artery A shown in Figure 16.

Thus, a stabilizer 10 has been described which is a simple design and is adapted to be easily handled and adjusted by the surgeon. It will be understood that various parts of the invention may be substituted by other parts of varying size and shape depending upon, for example, the type of surgery and the physical condition and characteristics of the patient. Further, the various embodiments described above can be used individually or in conjunction with other embodiments.

OPERATION

In use, the surgeon makes one or more openings in the chest wall of the patient to perform cardiac surgery and the proximal end 16 of the stabilizer 10 is inserted through the opening. The surgeon may use the connector 28 to connect the stabilizer 10 to a surgical instrument such as a rib spreader, or other supporting surface. The connector 28 allows the length and direction of the body 12 of the stabilizer 10 to be adjusted so that the engagement member 26 is positioned proximate to the area of the heart where the surgery is to be performed. The connector 28 is then locked into position by turning the cam lever 100 to hold the arm 12 in the desired position.

The surgeon then rotates the height adjustment knob 114 and the dial 124 such that the prongs 142 engage the outer surface of the heart with the desired amount force and the prongs 142 are separated the desired distance. Advantageously, the stabilizer 10 allows the prongs 142 to engage the heart, but adjustments to the stabilizer occur in an area away from the heart. Preferably, the surgeon then turns the vacuum source 164 on and adjusts the strength of the vacuum to positively engage the outer position of the heart with the prongs 142. The cardiac surgery is then performed. After the surgery is completed, the vacuum source 164 is turned off and the height adjustment knob 114 is turned to disengage the prongs 142 from the heart. The dial 124 is turned to return the prongs 142 to the closed position and the cam lever 100 is moved to release the universal joint 30. The stabilizer 10 can now be removed from the patient.

Although this invention has been described in terms of certain preferred embodiments, other embodiments apparent to those of ordinary skill in the art are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by the claims which follow.

WHAT IS CLAIMED IS:

1. A stabilizer for supporting a portion of the heart during cardiac surgery, comprising:

an elongated shaft having a distal end and a proximal end;

one or more prongs attached to said proximal end of said elongated shaft;

a control mechanism attached to the distal end of said elongated shaft, said control mechanism allows the location of said prongs to be adjusted; and

wherein said prongs engage the heart proximate the location where the cardiac surgery is to be performed to hold the portion of the heart in a relatively stable position.

2. The stabilizer of Claim 1 wherein said prongs are adapted to engage a beating heart.

3. The stabilizer of Claim 1 wherein said prongs have a generally thin, flat portion to engage the heart.

4. The stabilizer of Claim 1 wherein said prongs have a generally smooth surface to engage the heart.

5. The stabilizer of Claim 1 further comprising a connector attached to said elongated shaft, said connector allowing the stabilizer to be attached to a supporting surface.

6. The stabilizer of Claim 1 further comprising a conduit attached to said prongs, said conduit connected to a vacuum, wherein said vacuum provides a force which positively engages said prongs with the heart.

7. The stabilizer of Claim 1 wherein said control mechanism adjusts a lateral distance between said prongs.

8. A tool for supporting an organ upon which surgery is to be performed, comprising:

an elongated shaft having a distal end and a proximal end, said proximal end being inserted into the body of the patient and said distal end remaining outside of the body of the patient;

a control mechanism attached to said distal end of said shaft; and

an engagement member attached to said proximal end of said shaft;

wherein said control mechanism is located outside the body of the patient and controls the movement of said engagement member.

9. The tool of Claim 8 wherein said engagement member includes one or more prongs, said prongs are configured to engage the organ proximate the location where the surgery is to be performed.

10. The tool of Claim 9 wherein said one or more prongs includes two prongs, said two prongs are biased into a first position wherein said prongs are positioned proximate to each other.

11. The tool of Claim 10 wherein said control mechanism adjusts the distance between said two prongs.

12. The tool of Claim 10 further comprising a spreader, said spreader movable to change the spacing between said two prongs.

13. The tool of Claim 12 wherein said prongs have a proximal end attached to said elongated shaft; wherein said spreader is inserted between said proximal ends of said prongs; and wherein movement of said control mechanism adjusts a distance between said prongs.

14. The tool of Claim 9 wherein each of said one or more prongs include a generally thin, flat portion which engages the organ.

15. The tool of Claim 14 wherein said generally flat, thin portion has a generally smooth surface which engages the organ.

16. The tool of Claim 8 wherein said organ is the heart.

17. The tool of Claim 8 wherein said elongated shaft has a curved section to facilitate positioning of said engagement member within the body of the patient.

18. The tool of Claim 8 wherein said control mechanism adjusts the vertical positioning of the engagement member.

19. The tool of Claim 8 wherein said one or more prongs have an S-shaped upper portion.

20. The tool of Claim 8 further comprising a connector attached to said elongated shaft to attach the tool to a support surface.

21. The tool of Claim 20 wherein said support surface is a retractor.

22. The tool of Claim 20 wherein said connector includes a cam lever movable between a first position which allows rotation of said connector and movement of said elongated shaft, and a second position which prevents rotation of said connector and movement of said elongated shaft.

23. The tool of Claim 8 further comprising a conduit connected to each of said one or more prongs, said conduit connected to a vacuum source.

24. A stabilizer for supporting a portion of the heart during cardiac surgery, comprising:

an elongated shaft having a distal end and a proximal end, said distal end being inserted into the body of the patient and said proximal end remaining outside of the body;

one or more prongs for engaging the heart, each of said one or more prongs having a distal end and a proximal end, said proximal end of said prongs being mounted to said distal end of said elongated shaft; and

means for controlling the movement of said one or more prongs.

25. The stabilizer of Claim 24 wherein said means for controlling the distance includes a control mechanism attached to the distal end of said body.

26. The stabilizer of Claim 24 wherein each of said two prongs is mounted to the proximal end of said elongated body such that said prongs may be spaced apart from one another to provide stabilization of the portion of the heart.

27. A stabilizer for supporting a portion of the heart upon which surgery is to be performed, comprising:

an elongated shaft having a distal end and a proximal end; and

at least one generally flat, thin prong connected to said distal end of said elongated shaft, said prong having a generally smooth surface for engaging the heart.

28. The stabilizer of Claim 27 wherein said prong is mounted to the proximal end of said elongated body such that said prong may be spaced apart from another prong to provide stabilization of the portion of the heart.

29. The stabilizer of Claim 27 further comprising a control mechanism attached to said distal end of said elongated shaft, said control mechanism controlling the movement of said prong.

30. The stabilizer of Claim 27 further comprising a conduit connected to said prong, said conduit connected to a vacuum source.

31. The stabilizer of Claim 27 wherein said prong is adapted to hold the portion of a beating heart in a relatively stable position for cardiac surgery.

32. A method of performing cardiac surgery, comprising:

creating an opening in the chest wall of a patient;

providing a stabilizer, comprising:

an elongated shaft having a distal end and a proximal end;

a control mechanism attached to the distal end of said elongated shaft; and

one or more prongs attached to said proximal end of said elongated shaft;

inserting a portion of the stabilizer through said opening; and

manipulating the stabilizer so that said prongs engage the heart proximate the location where the cardiac surgery is to be performed to hold the portion of the heart in a relatively stable position.

33. The method of Claim 32 further comprising the step of spreading said prongs to engage the heart.

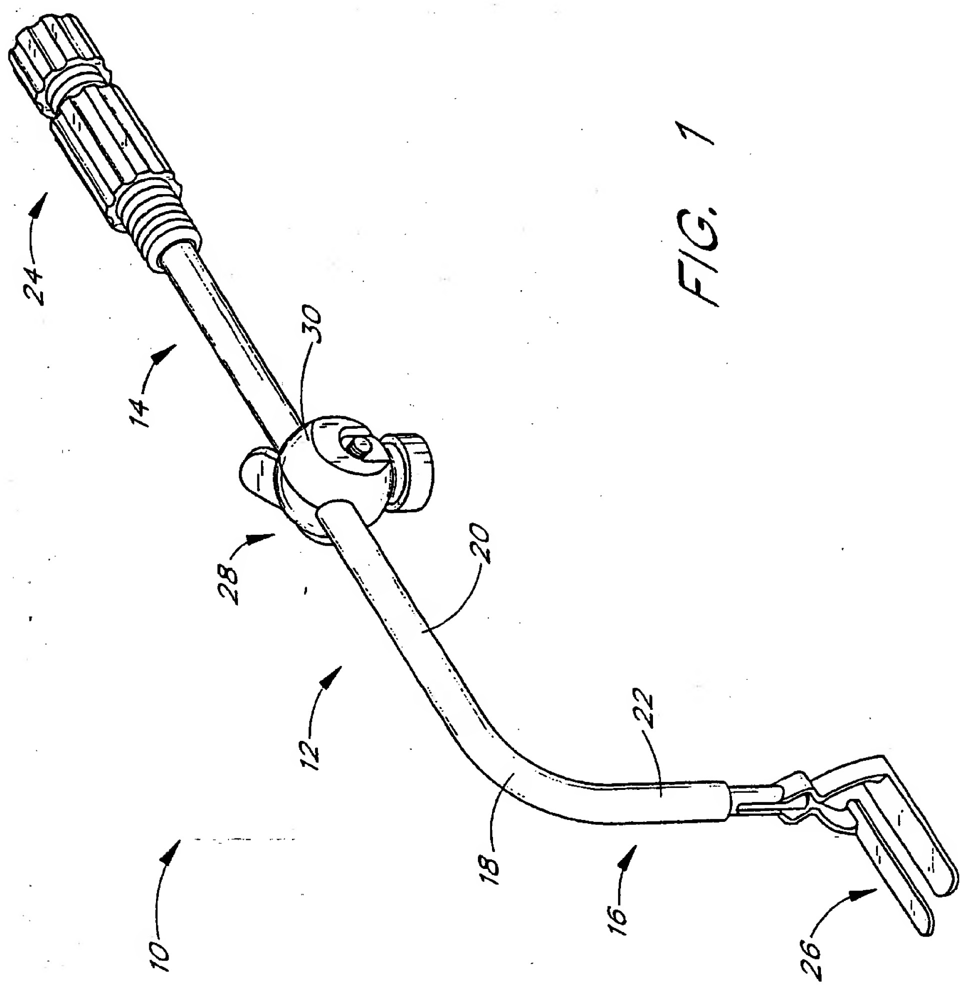

FIG. 1

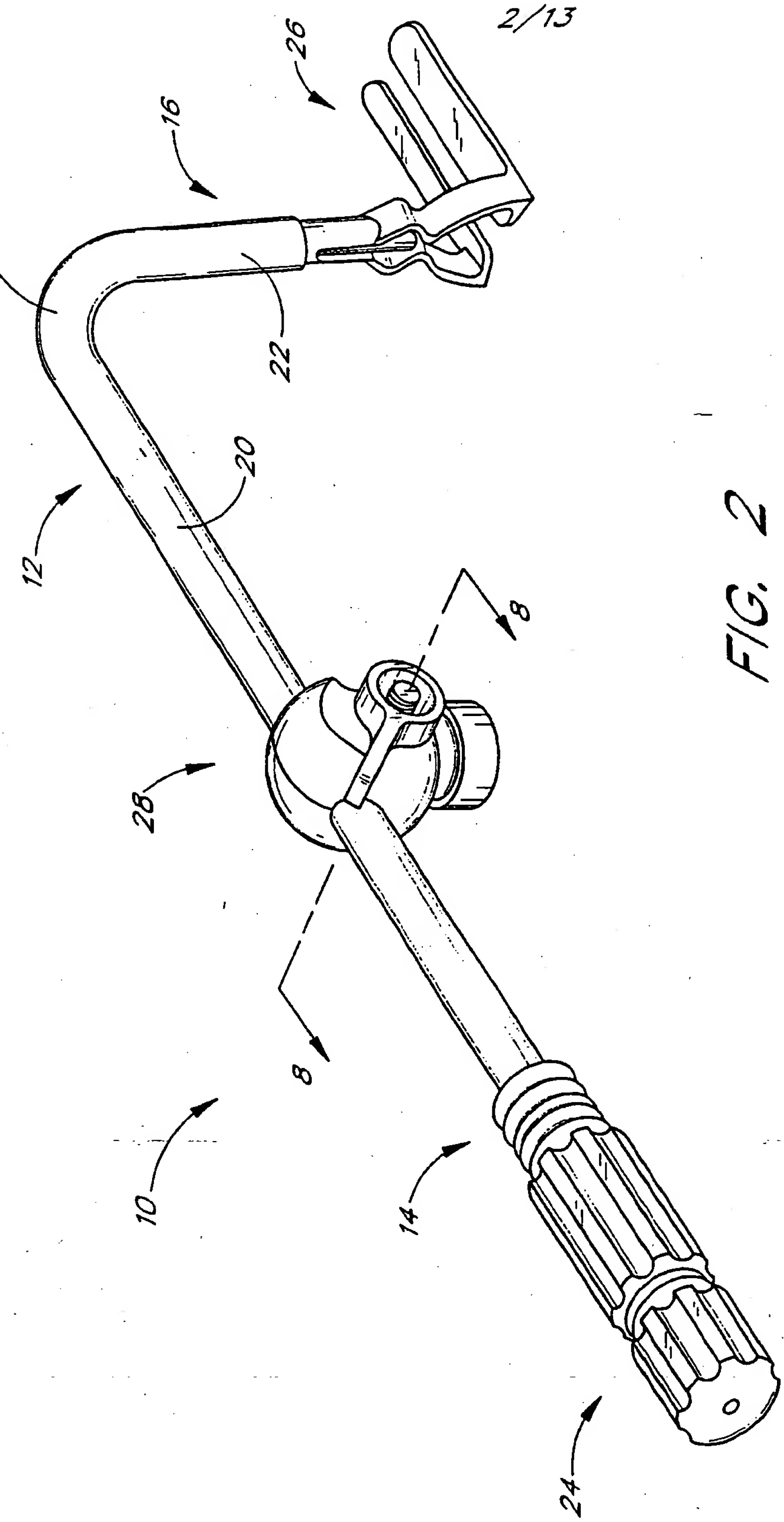

FIG. 2

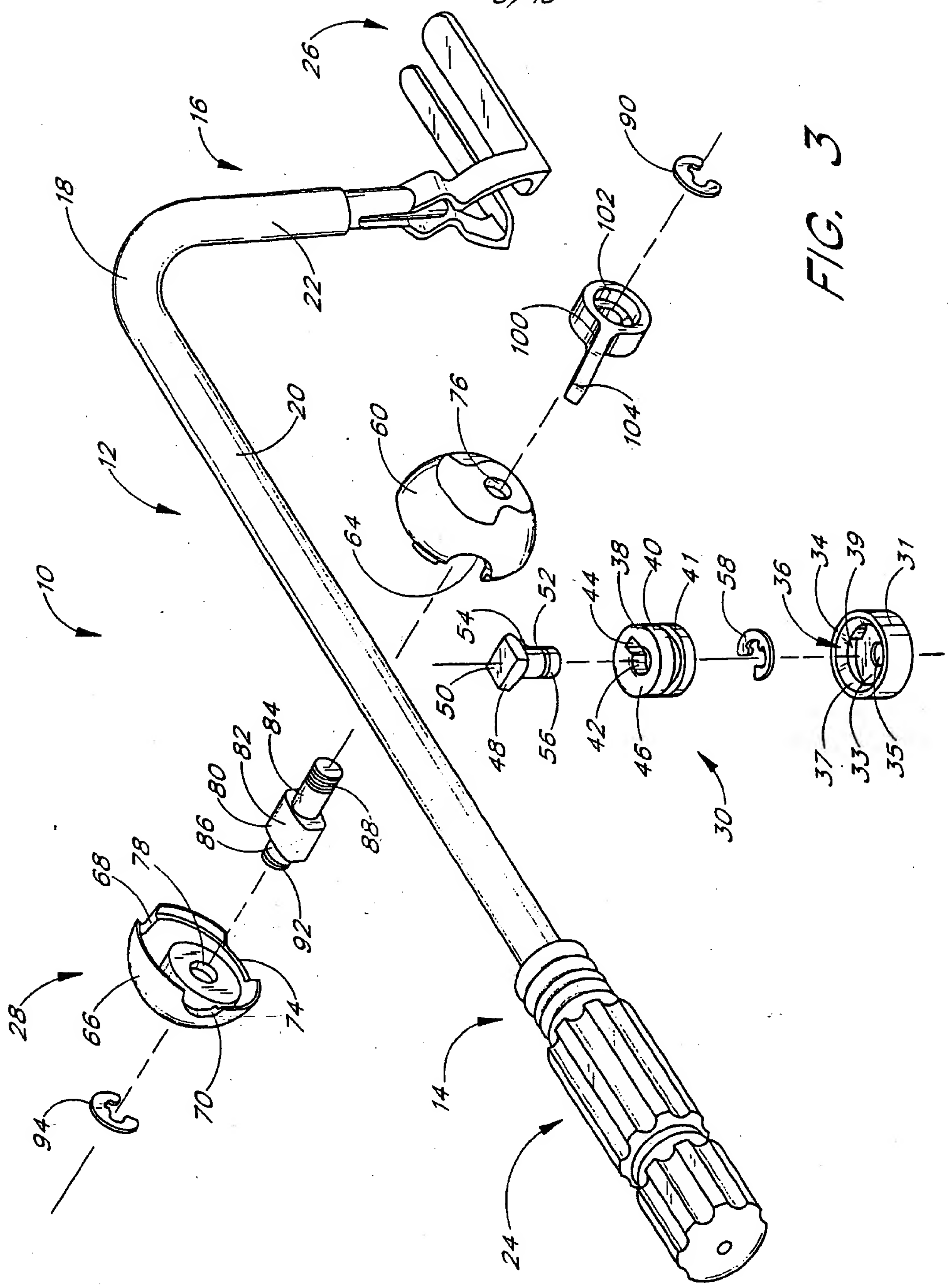
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FIG. 3

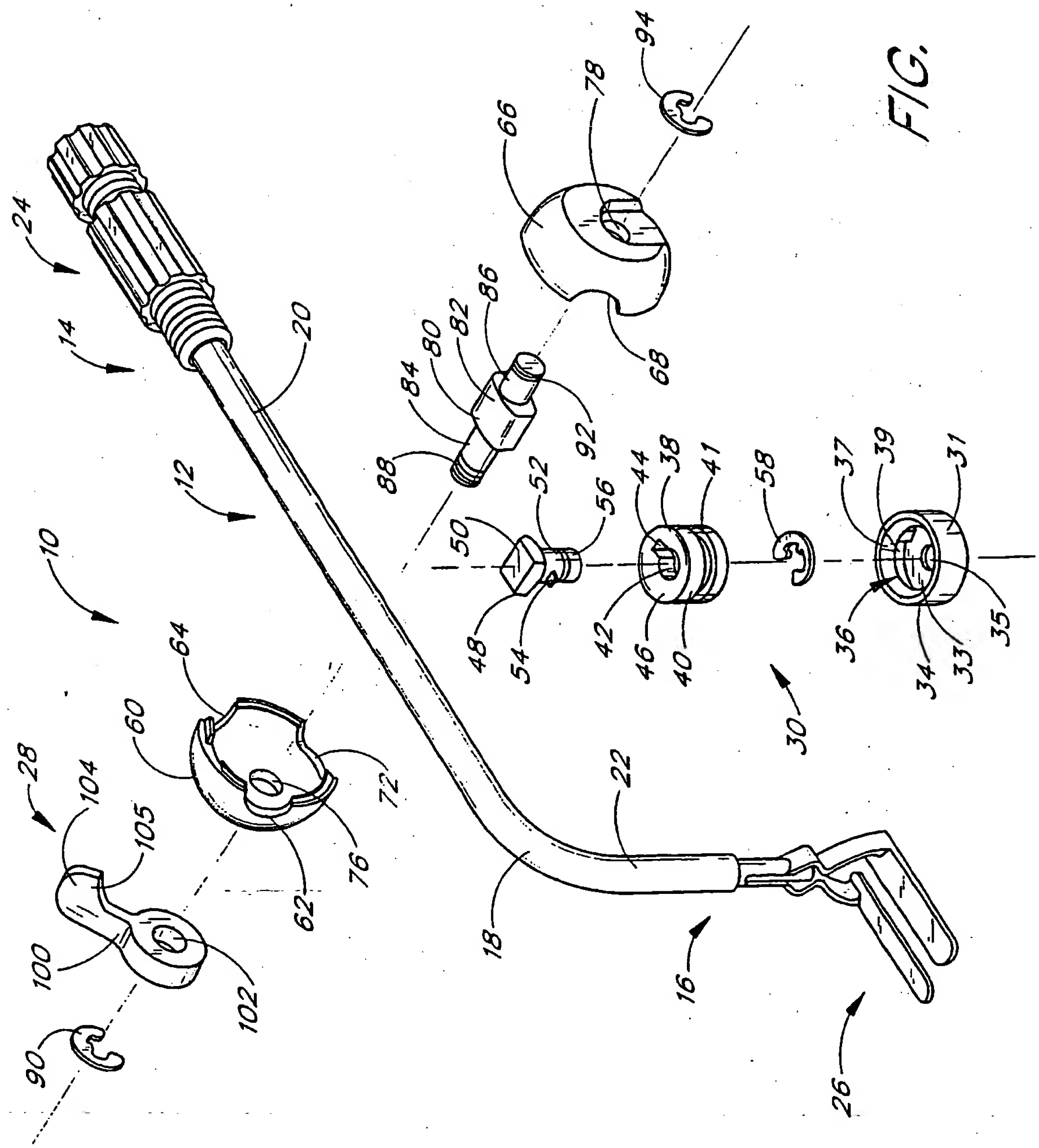
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FIG. 4

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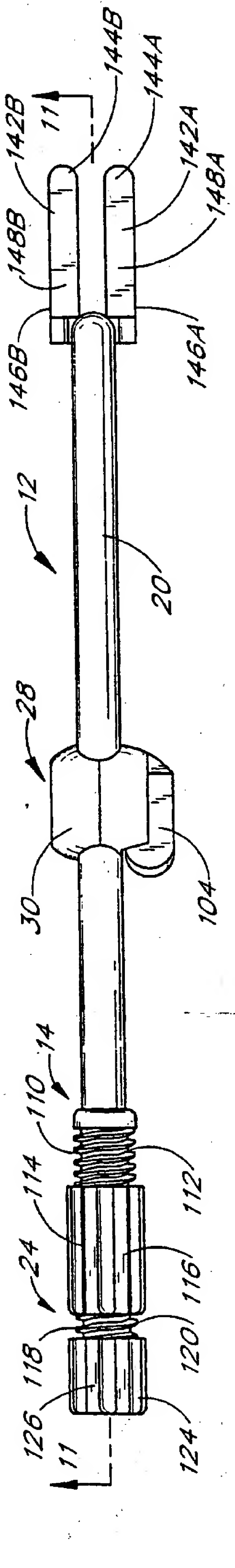

FIG. 5

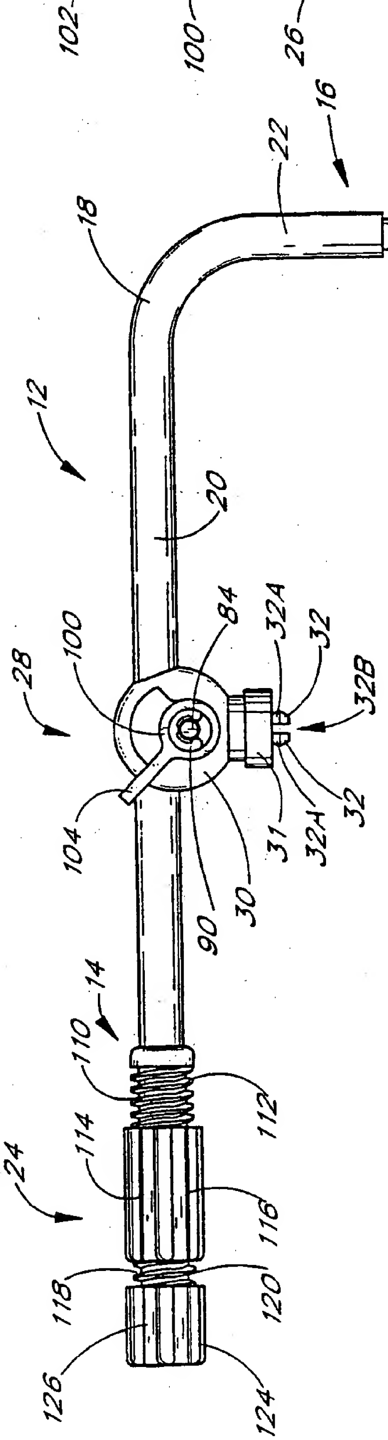

FIG. 6

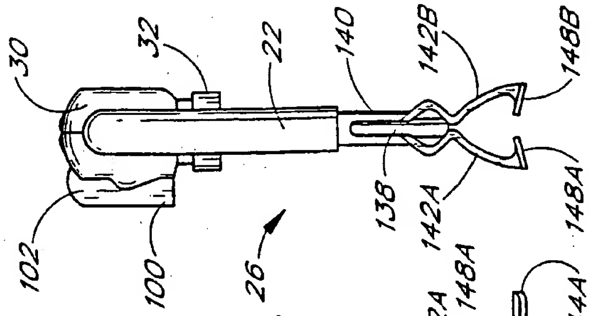

FIG. 7

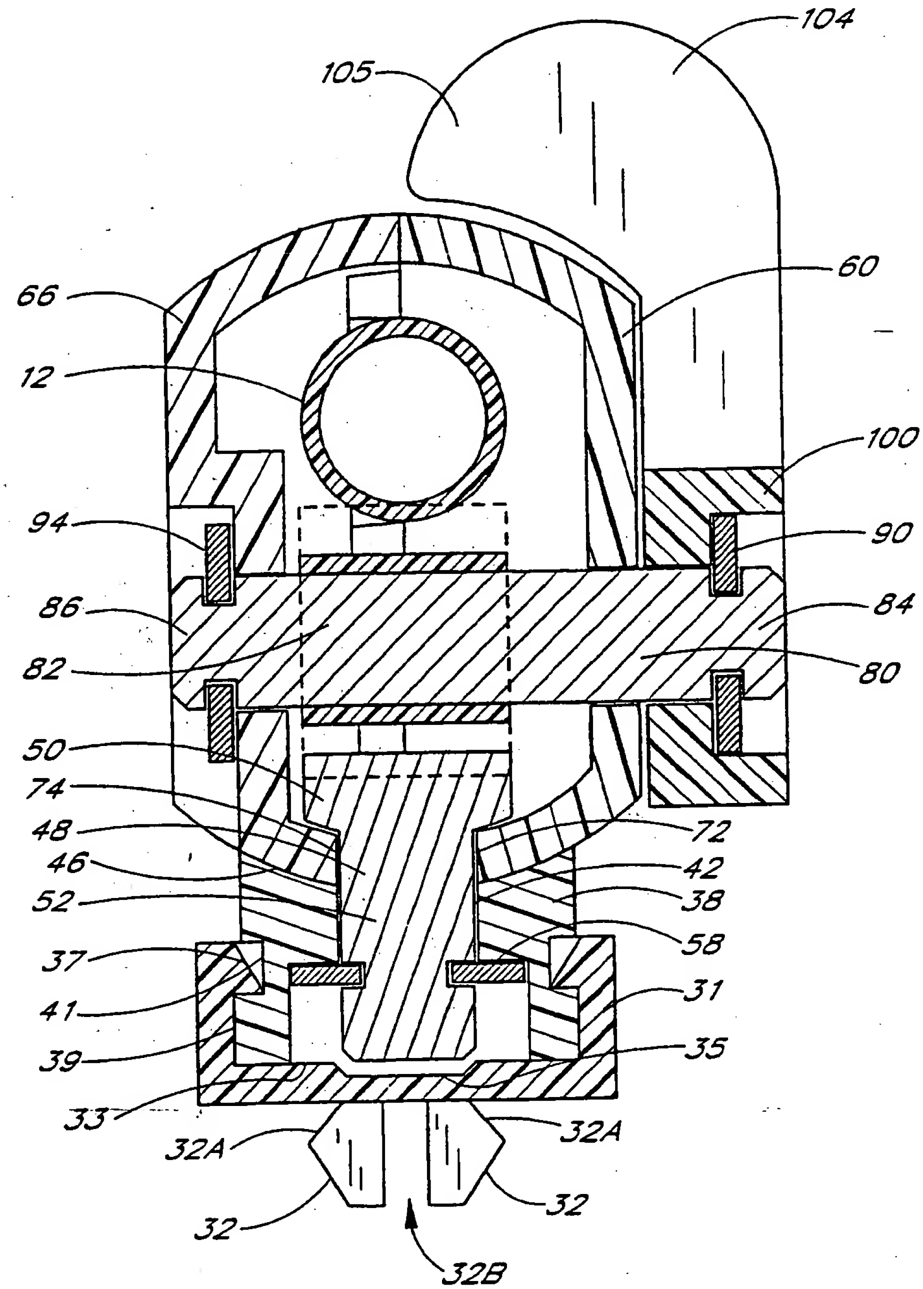
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FIG. 8

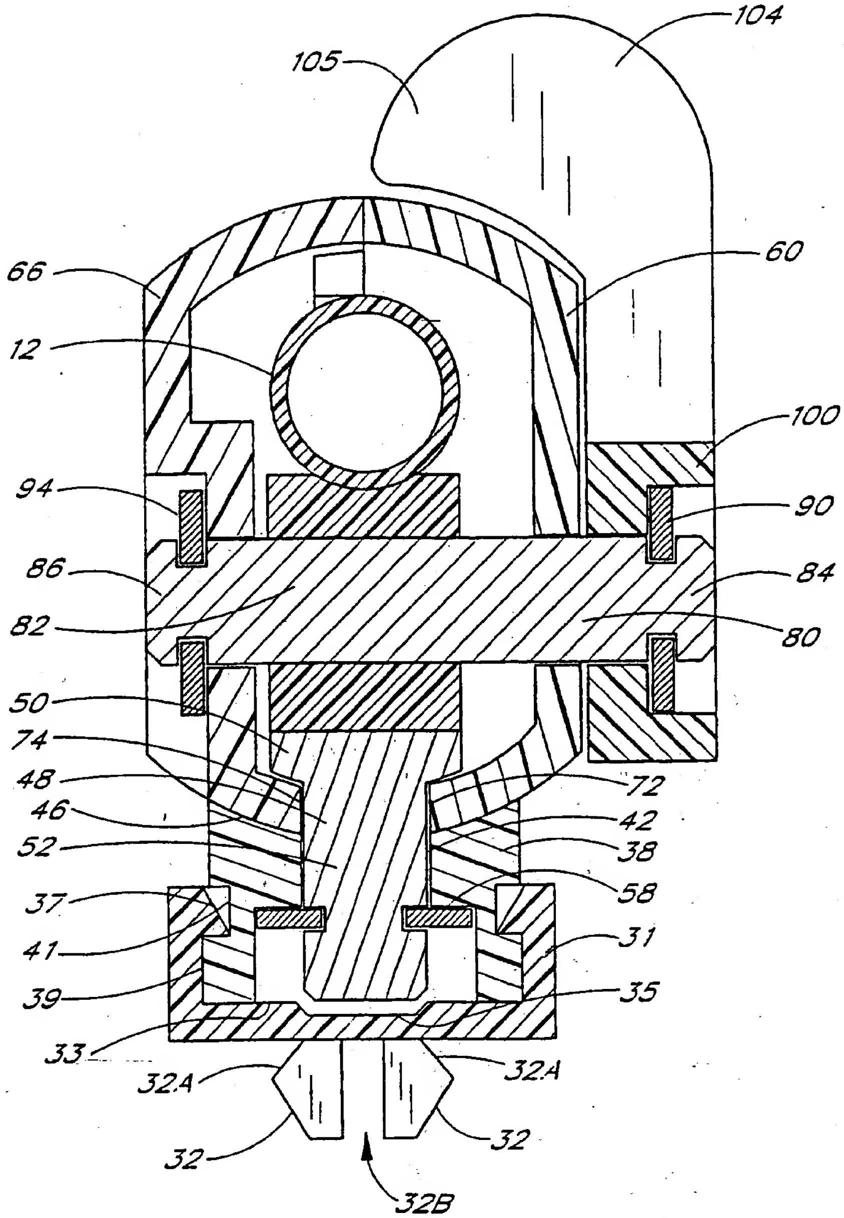
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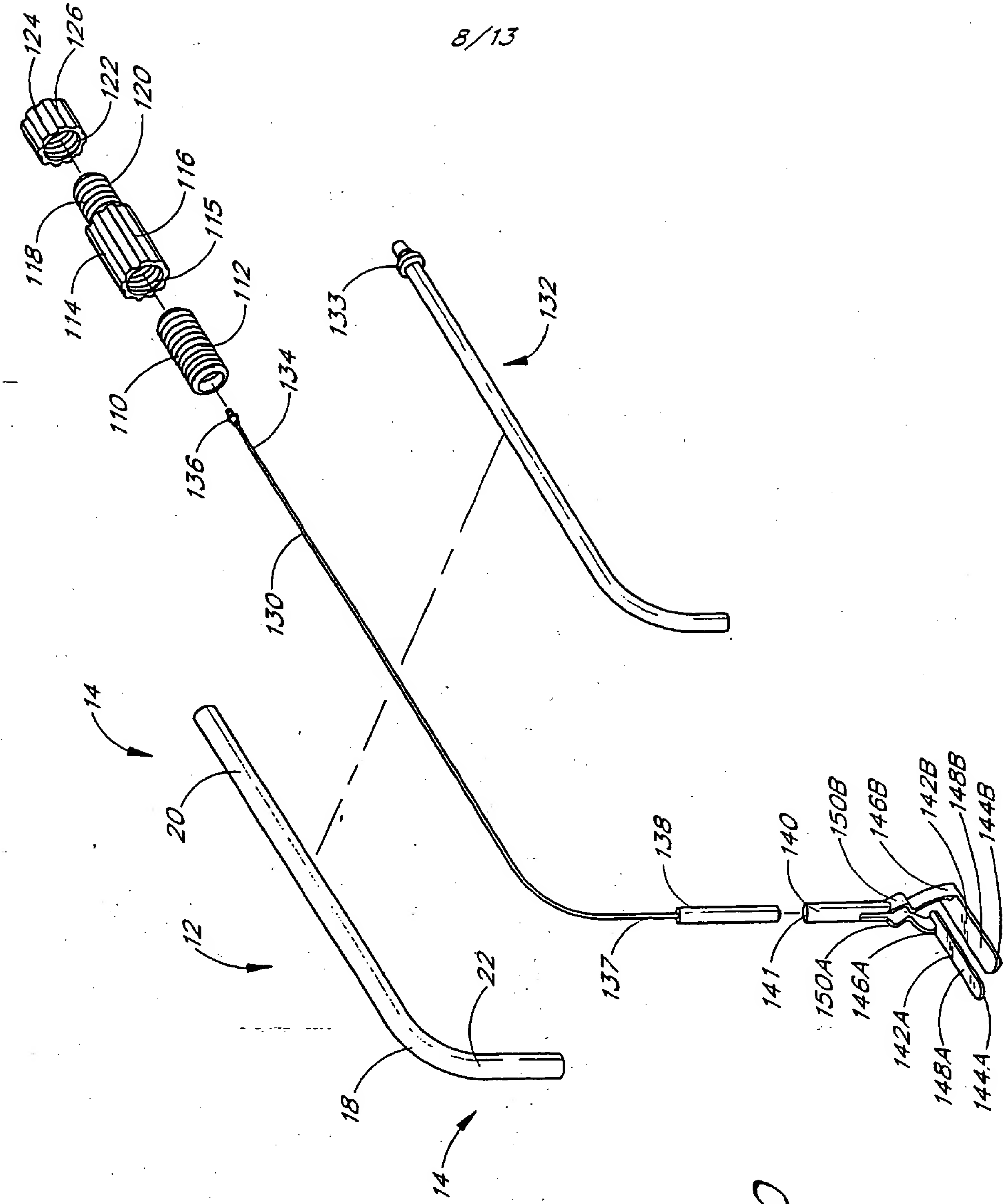
FIG. 9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144A

FIG. 10

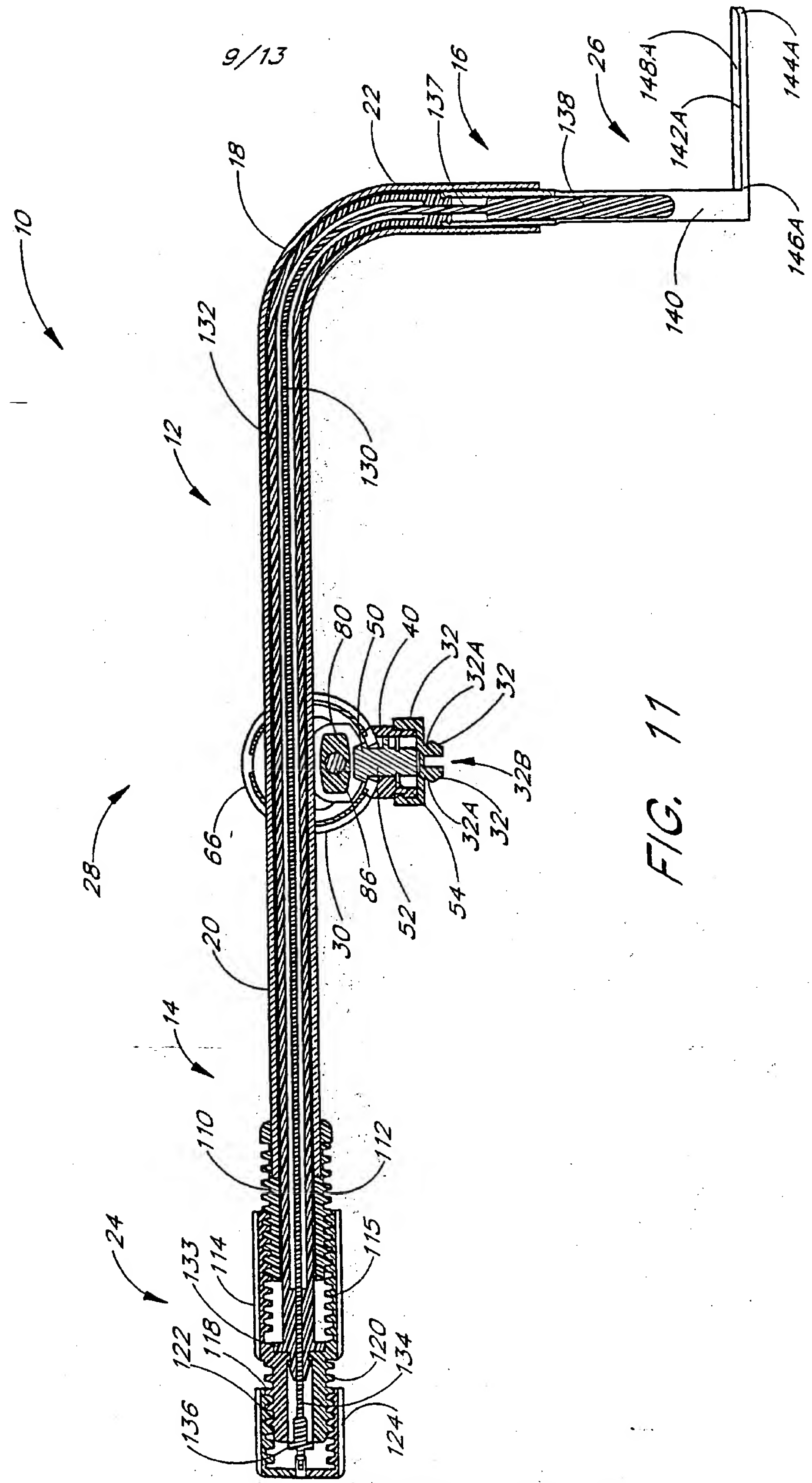
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FIG. 11

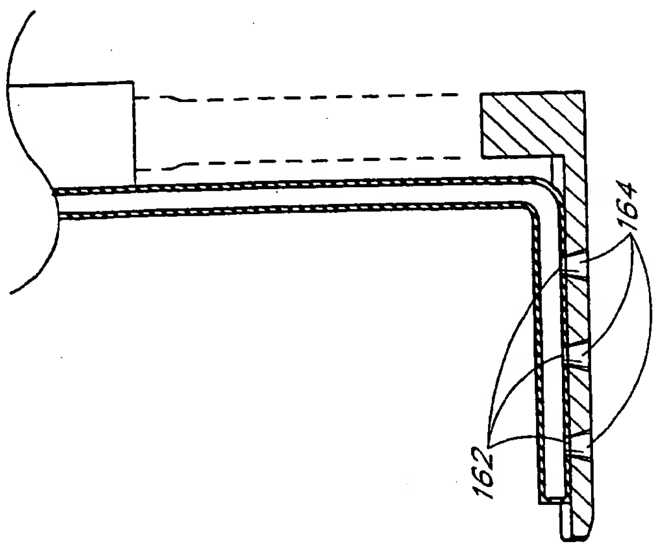
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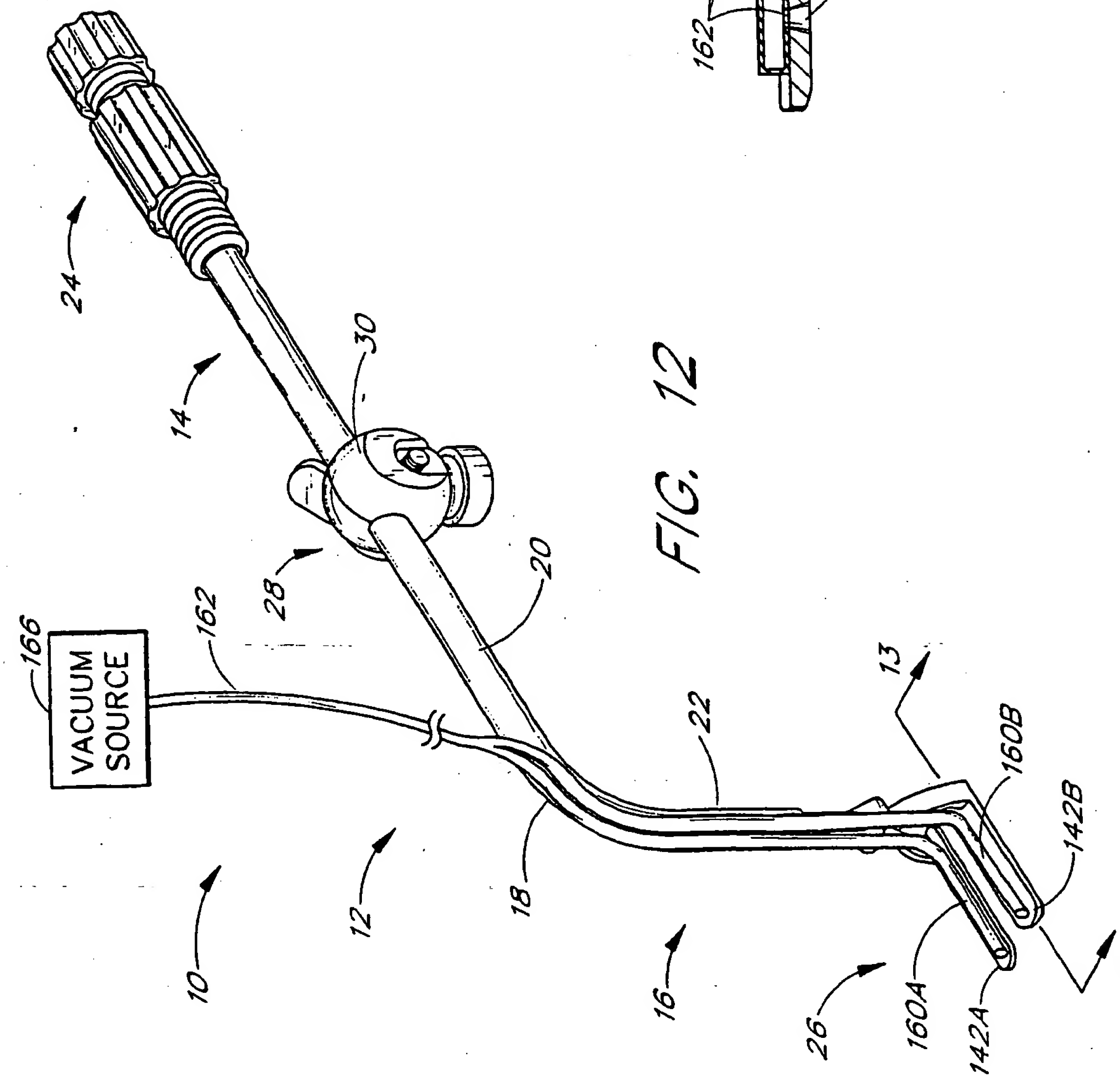
FIG. 13


VACUUM SOURCE
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142B

FIG. 12

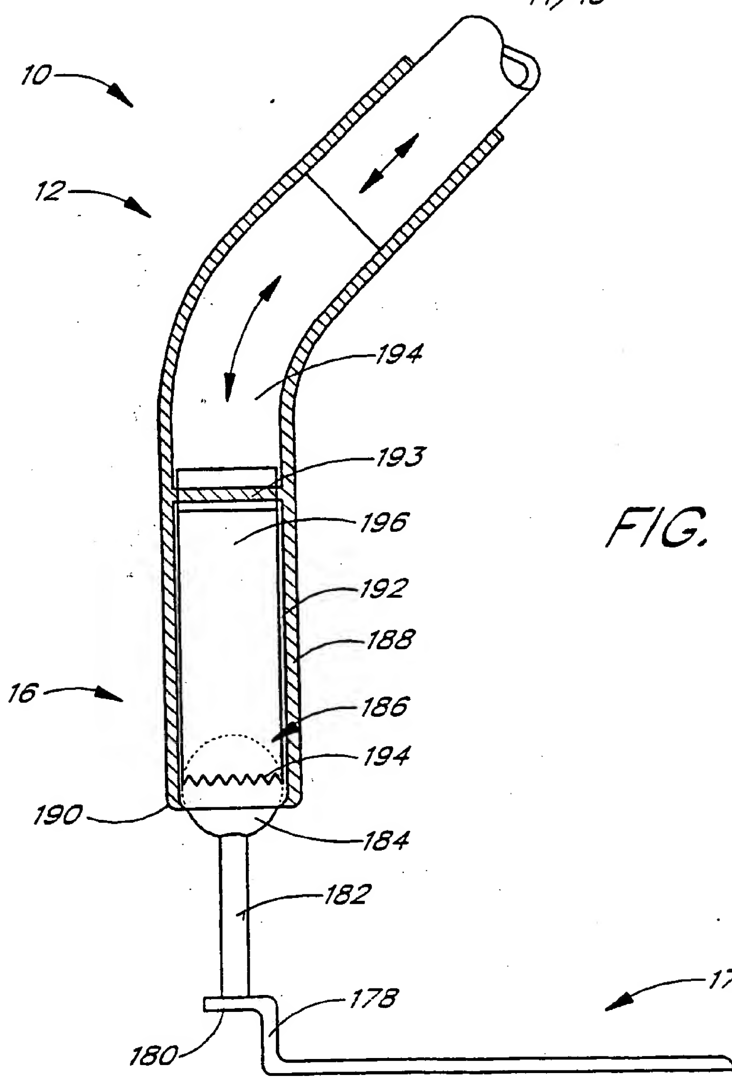
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FIG. 14

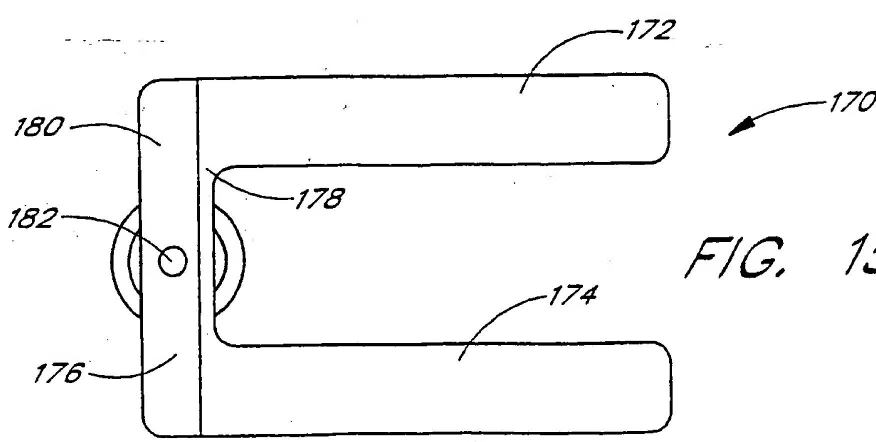
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FIG. 15

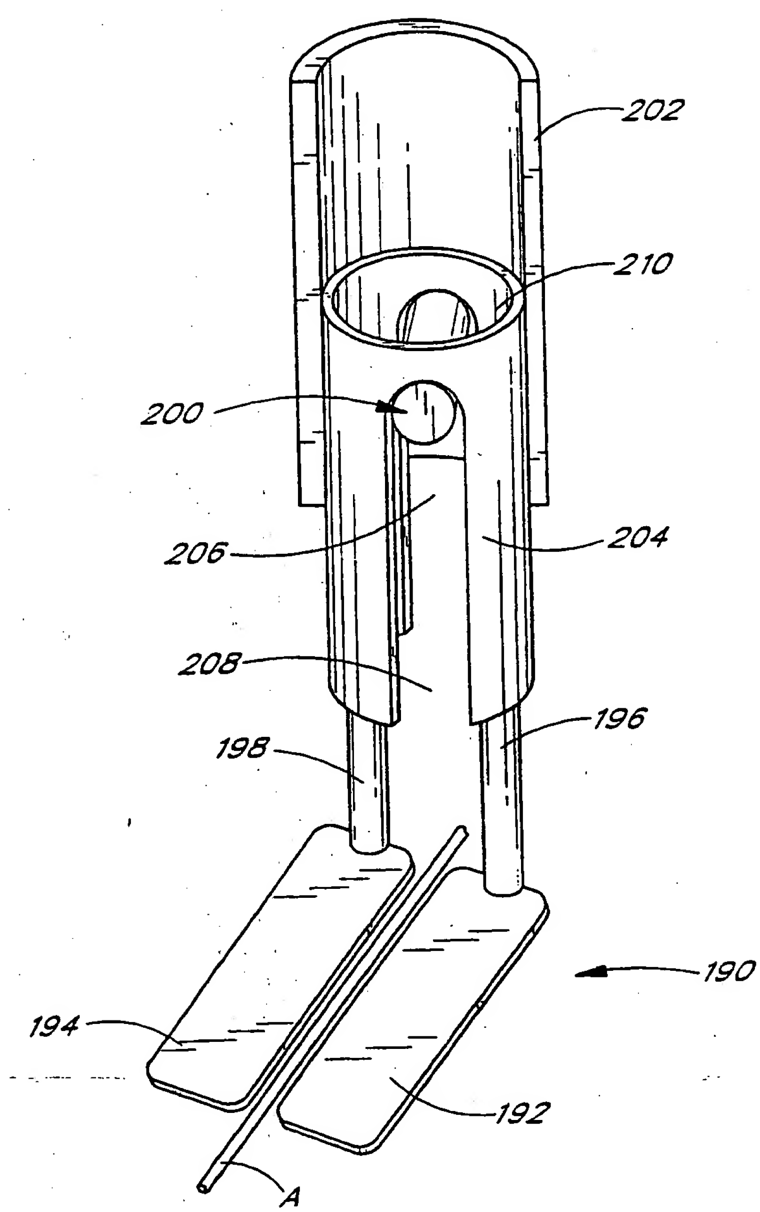

FIG. 16

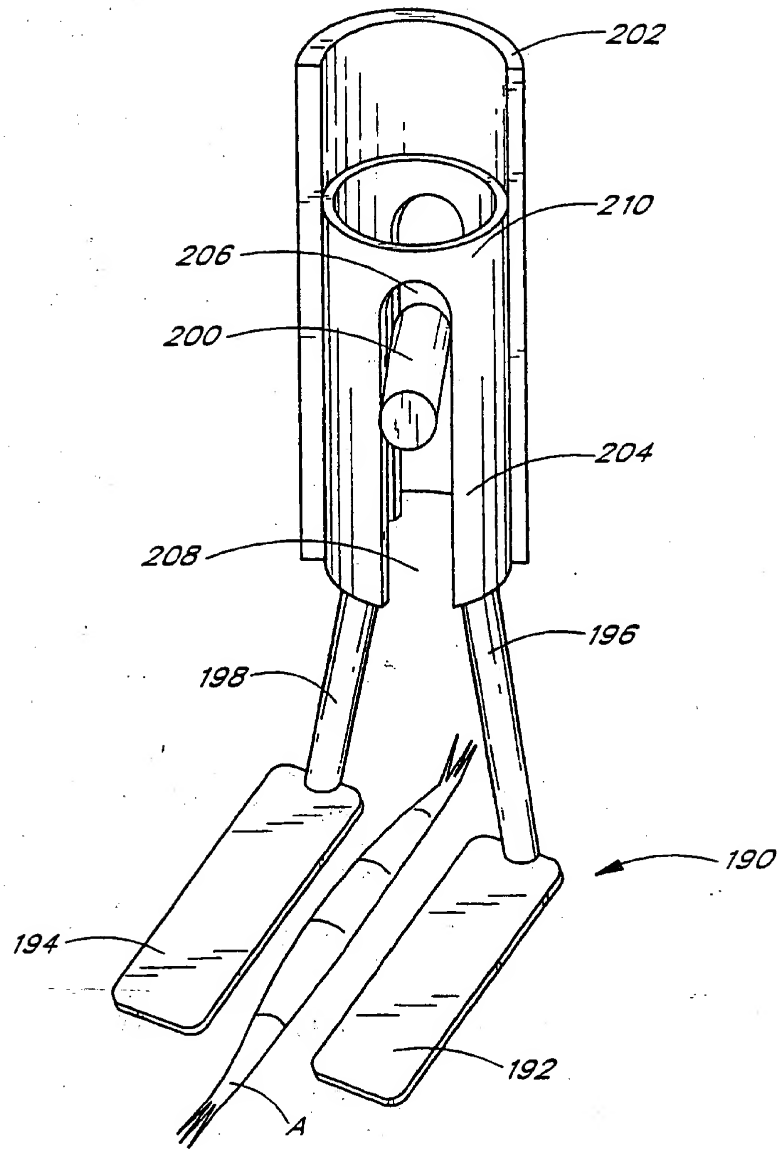

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19928

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/28
US CL :606/205-208
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/205, 206, 207, 208

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,618,307 A (DONLON et al.) 08 April 1997, Figs. 1 and 2.	1-33
X	US 5,630,821 A (KLAAS) 20 May 1997, Figs. 1-5.	1-4, 6-33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 NOVEMBER 1998

Date of mailing of the international search report

14 DEC 1998

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